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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/853,635	Applicant(s) OLSON, BENGT KRISTER	
	Examiner DR. Kailash C. Srivastava	Art Unit 1651	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/12/2002 (Paper Number 8)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *1-12,28,37-40 and 42-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-27, 29-36 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response filed 07/12/2002 (Paper Number 9) to election requirement in Office Action dated 06/04/2002 (paper Number 6) is acknowledged and entered.

2. Claims 1-64 are pending.

Restriction/Election

3. Applicant's election with traverse of Group II, Claims 13-27, 29-36 and 41 is acknowledged and entered. Applicant's traversal is on the grounds that Claims 1-64 pertain to a single invention and a search of all the groups (I-IV) as delineated in Office action mentioned *supra* would not place an additional burden on the examiner. This is not found persuasive because of the reasons of record in item 3 on pages 2-3 in Office Action of 06/04/2002 (paper Number 6). As pointed out in the citation referred to *supra*, there indeed are 4 different inventions because of their different classification and their recognized subject matter. Moreover, the search for each of the distinct inventions of Groups I-IV is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. The restriction requirement is, therefore, still deemed proper and is made FINAL.

Accordingly, Claims 1-12, 28, 37-40 and 42-64 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 13-27, 29-36 and 41 are examined on merits.

Objection to Specification

5. The disclosure is objected to because of the following informalities: Terms (e.g., MTT, GT, FGT, MMP, Method C etc.) are not explicitly defined in the specification.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 13, 17, 19, 30, 32, 34-36 and 41 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 13 is rendered vague and indefinite because of the phrase, "one or more compounds extractable therefrom". This phrase, in and of itself does not define its metes and bounds. Appropriate correction is required.

- The recitation, "derivative" in claim 13 is unclear as well as confusing, and therefore indefinite because this recitation does not clearly define as to how similar a material should be of the base material (i.e., cartilage in this case) to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Appropriate correction is required.

- Claim 13 is rendered vague and indefinite because of the phrase, "said composition increases collagen synthesis". This phrase renders the claim indefinite because it lacks quantifying units to measure the increase in collagen synthesis. Appropriate correction is required.

- Claim 13 is rendered vague and indefinite because of the phrase, "Test Method A". This test method is neither defined in the specification, nor in the claims. An artisan of ordinary skill would not know the metes and bounds for this test to be able to practice the claimed invention. Applicant is required to describe "Test Method A".

- Claim 19 is rendered vague and indefinite because of the phrase "from grape seed of *Vitis vinifera*". Applicant is advised to use the phrase "from grape seeds" or from "seeds of *Vitis vinifera*".

- Claim 23 is rendered vague and indefinite because of the phrase, "wherein the tomato variety is *Lycopersicon esculentum*". Applicant is advised that *Lycopersicon esculentum*" is tomato and applicant should therefore, use the phrase, "wherein the tomato variety is *Lycopersicon esculentum*, variety ... (e.g., *esculentum*).

- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term " *Lycopersicum aesculentum*" in

claim 23 is used by the claim to mean "*Lycopersicon esculentum*" which is the accepted botanical name for tomato (see for e.g., Johnson, T., 1999, CRC Ethnoboany Desk Reference, CRC Press LLC, Boca Raton, FL., U.S.A., Page 499, Column 2, entry 16162). Appropriate correction should be made.

- Claim 30 is unclear by the abbreviation"MMP-1". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

- Claim 30 is rendered vague and indefinite because of the phrase, "Test Method B". This test method is neither defined in the specification, nor in the claims. An artisan of ordinary skill would not know the metes and bounds for this test to be able to practice the claimed invention. Applicant is required to describe "Test Method B".

- Claim 32 is rendered vague and indefinite because of the phrase, "Test Method C". This test method is neither defined in the specification, nor in the claims. An artisan of ordinary skill would not know the metes and bounds for this test to be able to practice the claimed invention. Applicant is required to describe "Test Method C".

- Claims 35 and 36 are rendered indefinite because of the limitations "lycopene" and "grape seed extract" in Claim 35 and "lycopene", "grape seed extract" and "cartilage extract" in Claim 36". There is an insufficient antecedent base for cited limitations in claims 35 and 36.

- Claim 41 is rendered indefinite because of the phrases, "slow release" and "normal release". These terms are subjective and therefore, do not establish any metes and bounds to distinguish one term from another. An artisan skilled in the art will not be able to distinguish among the terms as discussed above. Applicant is requested to define these terms.

Claim Rejections – 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

9. Claims 13-20, 24 and 32 are rejected under 35 U.S.C. §102(b) as anticipated by Greenberg (U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402).

Claims recite a composition to enhance collagen synthesis and reduce formation of advanced glycosylation end products. The said composition comprises cartilage extract or compounds extractable from cartilage and hydrophilic and lipophillic antioxidants, wherein said antioxidants are obtained from a synthetic or natural source. The said antioxidants are comprised of plant extract components, more specifically oligomeric procyanidol, lycopene and carotenes.

Greenberg discloses a dietary supplement composition comprising chondroitin sulphate, extracts from *Ginkgo biloba* and *Silybum marianum*, proanthocyanidins, vitamin E and β-carotene (Column 2, Lines 63-67; Column 3, Lines 36-40). Thus, Greenberg discloses a composition comprising cartilage extract compound (e.g., chondroitin sulphate), lipophilic (e.g., vitamin E and β-carotene) and hydrophilic (e.g., proanthocyanidin from red wine grapes and extract of *Ginkgo biloba*) antioxidants. Since proanthocyanidin obtained from wine grapes is a component of the said composition, the said composition also comprises oligomeric procyanidol (See Bombardelli et al., Page 7, Lines 1-2). Even though Greenberg does not explicitly disclose enhancement of collagen synthesis and reduction in formation of advanced glycosylation end products because of administering his dietary supplement composition to an individual, the claims are anticipated by the Examiner-cited prior art reference because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight. Furthermore, administration of some quantity of Greenberg's dietary supplement composition would upon its ingestion by an individual inherently enhance collagen synthesis and reduce formation of advanced glycosylation end products by the same index as is recited in the claimed invention because the quantity of composition administered to obtain the intended effect is not recited in the claims. Therefore, the prior art composition (the disclosed dietary supplement composition) inherently must function as claimed because the said prior art composition is comprised of same components and is being administered in the same way as the claimed composition (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

Please note that Bombardelli et al., is cited to merely support the constituents of hydrophilic and lipophilic antioxidants and not as a prior art reference.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

11. Claims 13-27, 29-36 and 41 are rejected under 35 U.S.C. § 103 (a) as obvious over Greenberg (U.S. Patent 5,569,458) in view of Bombardelli et al (EP 0,6559,402) and Kosbab (WO 00/07607).

Claims recite a composition to enhance collagen synthesis and reduce formation of advanced glycosylation end products. The said composition comprises cartilage extract or compounds extractable from cartilage and hydrophilic and lipophyllic antioxidants, wherein said antioxidants are obtained from a synthetic or natural source. The said natural source are plant extract components, more specifically oligomeric procyanidol, lycopene and carotenes. The source for said plant extracts are anyone of following plants: *Aesculus hippocastanum*, *Camelia sinensis*, *Cardus marianum*, *Ginkgo biloba*, *Lycopersicon esculentum* (i.e., tomato), pine bark, *Silybum marianum*, *Vaccinium myrtilius* and *Vitis vinifera*.

As discussed in item 9 *supra* Greenberg discloses a dietary supplement composition comprising chondroitin sulphate, extracts from *Ginkgo biloba* and *Silybum marianum*, proanthocyanidins, vitamin E and β-carotene (Column 2, Lines 63-67; Column 3, Lines 36-40). Thus, Greenberg discloses a composition comprising cartilage extract compound (e.g., chondroitin sulphate), lipophilic (e.g., vitamin E and β-carotene) and hydrophilic (e.g., proanthocyanidin from red wine grapes and extract of *Ginkgo biloba*) antioxidants.

Greenberg, however, does not disclose in his composition grape seed extract and procyanidole oligomers, different plants as the natural source of antioxidants, different sources of lipophilic antioxidants (e.g., lycopene, xanthophylls, carotenes) and tomato extract as the source of lipophilic antioxidants. Furthermore, he does not distinguish among

the hydrophilic and lipophilic antioxidant components of his dietary supplement composition. Greenberg also does not disclose that the said dietary supplement composition reduces harmful effects of oxygen free radicals.

Bombardelli et al., disclose a composition comprising hydrophilic and lipophilic antioxidants, wherein the sources for hydrophilic antioxidants are: silymarin, proanthocyanidin and procyanidole oligomers extracted from *Aesculus hippocastanum*, *Camelia sinensis*, *Cardus marianum*, *Ginkgo biloba or Vitis vinifera*. In the said composition the sources for lipophilic antioxidants, among others, are: β-carotene, lycopene and vitamin E wherein *Lycopersicon esculentum* (tomato, see Johnson, T., Page 499, Column 2, entry 16162) is the source of lycopene (Page 6, Lines 47-53 and Page 7, Lines 1-4). Bombardelli et al., further disclose that the said composition comprising mixtures of hydrophilic and lipophilic antioxidants is useful in prevention of "physiopathological" conditions related to overproduction of free radicals (Abstract, Lines 4-6). Thus, bombardelli et al., clearly define the sources of hydrophilic and lipophilic antioxidants in their composition, disclose that the sources are natural and that the composition reduces harmful effects of free radicals.

None of the prior art references cited *supra* clearly disclose that their composition enhances collagen synthesis. The references also do not disclose cartilage or pine bark extract as the components for their compositions.

Kosbab, however, discloses a composition comprising cartilage or chondroitin sulphate (Page 24, Line 6) and antioxidant containing plant extracts, wherein antioxidants are: carotenoid, flavonoids and Vitamin E (page 43, Lines 1-11). The sources for carotenoids in the said composition are β-carotene, lutein, lycopene, zeaxanthin (Page 24, Lines 24-25) and sources for flavonoids are: extracts of bilberry, *Ginkgo biloba*, grape seed and pine bark (Page 23, Lines 26-32 and Page 24, Lines 10 and 20-21). The said composition has an antioxidant effect and stimulates collagen synthesis (Page 43, Lines 8-9 and Page 44, Lines 10-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Greenberg's composition by incorporating beneficial teachings from Bomberilli et al., and Kosbab, because each one of the cited prior art references teach a composition comprising hydrophilic and lipophilic antioxidants (Column 2, Lines 63-67; Column 3, Lines 36-40), wherein the sources for those antioxidants are natural (i.e., plant extracts) and Bombardelli et al., teach that the said composition (Page 6, Lines

47-53 and Page 7, Lines 1-4) is effective against reducing those ailments that are caused by free radicals (Abstract, Lines 4-6), and Kosbab further discloses that the said composition is comprised of antioxidants and cartilage and enhances collagen synthesis (Page 23, Lines 26-32; Page 24, Lines 6, 10, 20-21 and 24-25; page 43, Lines 1-11 and Page 44, Lines 10-14)

One having ordinary skill in the art would have been motivated to modify Greenberg's dietary supplement composition according to the beneficial teachings from Bombardelli et al., because Bombardelli et al., beneficially distinguish sources of hydrophilic and lipophilic antioxidants, and indicate the natural sources (plant species and extracts from those plant species) for those antioxidants and further according to Kosbab's beneficial teachings because Kosbab teaches a composition comprising cartilage, an extractable compound from cartilage (chondroitin sulphate) and antioxidants obtained from natural sources to enhance collagen synthesis.

None of the prior art references cited above teach the methods to evaluate effects of their compositions on enhanced collagen synthesis, reduced formation of advanced glycosylation end products, or reduction of harmful effects of oxygen free radicals. Furthermore, the concentration of individual antioxidant components or cartilage in the aforementioned prior art references is either not disclosed or is not the same as in the claimed invention. However, the adjustment of particular conventional working conditions (e.g., concentration of individual components comprising a given composition and methods to evaluate different effects of the said composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

CONCLUSION

12. No Claims are allowed. However, Claim 27 still reads on a singular synthetic component as the source for antioxidants and if written as an independent claim or part of an independent claim drawn to a specific antioxidant source, may be allowable subject matter.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

September 19, 2002

CHRISTOPHER R. TATE
PRIMARY EXAMINER